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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/975,812 | 10/11/2001 | Gavril Pasternak | 830010-2002.2 | 9302 |

20999 7590 02/26/2002

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

[REDACTED] EXAMINER

BAHAR, MOJDEH

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1617

DATE MAILED: 02/26/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/975,812 | PASTERNAK ET AL. |
| | Examiner | Art Unit |
| | Mojdeh Bahar | 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 January 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 11-26 is/are pending in the application.

4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 11-13 and 16-26 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

The applicant's response to the restriction requirement of 12/10/01 is acknowledged.

Applicant's election with traverse of the invention of Group I, claims 11-26 and the anesthetic specie, lidocaine, and the analgesic, morphine, in Paper No. 4 submitted January 29, 2002 is acknowledged. The traversal is on the ground(s) that these two groups do not have different modes of operation because they have common elements. Note that the showing of different modes of operation is based on the fact that Group II claims are drawn to a composition comprising an additional therapeutic compound, namely an NMDA receptor antagonist whereas Groups I claims are drawn to a composition comprising two (rather than 3) therapeutic compounds.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-15 are withdrawn from consideration since they are drawn to non-elected species.

Claims 11-13, and 16-26 are herein examined on the merits in so far as they read on the elected specie.

Claim Objections

Claim 13 is objected to because of the following informalities: The employment of parenthetical expressions: "(DAMGO)", "(DPDPE)", "(DSLET)" in the claim is considered informal. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 contains the trademark/trade names “U50,488”, “U69,593”. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-15 and 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein (USPN 5,948,389) and of Saito et al.

Stein (USPN 5,948,389) teaches a method for enhancing the analgesic effects of locally applied opioid analgesic or anesthetic agent, see claim 1, col. 10 in particular. Stein also teaches morphine as an opioid analgesic and lidocaine as a local anesthetic agent, see claims 3 and 5, col. 10 in particular. Stein also teaches that the active ingredients in its compositions are present in an amount of 0.5% to 95% by weight of composition, see col. 7, lines 52-55. Finally Stein teaches that its compositions can be applied locally/topically in different formulations, see col. 7, lines 56-59.

Saito et al. teaches that intrathecal co-administration of morphine and lidocaine synergistically potentiated the antinociceptive effects of each agent, see abstract.

Stein (USPN 5,948,389) and Saito et al. taken together do not teach the employment of a single **topical** composition comprising both morphine and lidocaine in their analgesic method.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a single topical composition comprising both morphine and lidocaine in a method of providing analgesia.

One of ordinary skill in the art would have been motivated to employ a single topical composition comprising both morphine and lidocaine in a method of providing analgesia because they are known to synergistically potentiate the antinociceptive effects of each other. Note that intraconversion of dosage forms and optimization of amounts are within the skill of the artisan and are therefore obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
February 21, 2002

Minna Moezie
MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600